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Patrick Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038				
EXAMINER				
SCHELL, LAURA C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,545

Applicant(s)

DIMATTEO ET AL.

Examiner

LAURA C. SCHELL

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-28 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 22 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 16-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date 12/26/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Igarashi et al. (US Patent No. 7,282,041). Igarashi discloses a distal tip for a catheter (Fig. 23) comprising: first and second lumens (13 and 14, respectively) extending therethrough, wherein in a operative configuration, the first and second lumens are coupled to first and second lumens of a dual lumen catheter; a partition separating the first lumen from the second lumen (Fig. 23 be shows the cross section which shows the partition separating lumens 13 and 14, which is also shown in Fig. 23a); a first opening (71) fluidly connected to the first lumen (connected to lumen 13) for inflow of fluid from a body lumen into which the distal tip is inserted in a normal mode of operation and for outflow of fluid there into in a reverse mode of operation (Fig. 23a discloses that the fluid flow normally is into opening 71 and if reversed the flow would exit the catheter at 71); a second opening (81) fluid connected to the second lumen (connected to 14), the second opening being disposed distally from the first opening and separated therefrom

by a selected stagger distance for outflow of fluid therefrom when the catheter is in the normal mode of operation and for inflow of fluid from the body lumen in a reverse mode of operation (Fig. 23a discloses that the fluid flow is normally out of opening 81 but if reversed the flow would enter opening 81 and flow into the catheter); a contoured flow deflection element directing, in the reverse mode of operation outflow from the first opening away from the second opening (element 54 in lumen 13 as shown in Fig. 23a, is angled such that in the reverse mode the flow would hit the deflection element and be directed away from the second opening); a contoured outlet portion of the second opening reducing an outflow velocity therefrom in the normal mode of operation (both portion 54 in lumen 14 and portion 53 act to help slow the outflow velocity by interfering the fluid's "normal" flow direction); and side walls extending away from the partition on the same side as the first opening to create a channel between the first opening and the contoured flow deflection element (Fig. 23 b discloses walls extending on both sides of opening 71, these walls creating a channel between the opening of 71 and the contoured flow deflection element 54).

In reference to claim 2, Igarashi discloses that the first and second openings (71 and 81) are disposed on opposite sides of the distal tip with respect to a longitudinal axis thereof (Fig. 23a).

In reference to claim 3, Igarashi discloses that the first and second openings have orifices extending in planes angled with respect to a longitudinal axis of the distal tip (Fig. 23a).

In reference to claim 4, Igarashi discloses that the contoured flow deflection element (54) is adapted to direct outflow from the second opening away from the first opening in the normal mode of operation (Fig. 23a).

In reference to claim 5, Igarashi discloses an atraumatic tip (53) formed at a distal end of the distal tip.

In reference to claim 6, Igarashi discloses that the first opening includes a first ramp portion deflecting outflow therefrom away from a longitudinal axis of the distal tip in the reverse mode of operation (Fig. 23a).

In reference to claim 8, Igarashi discloses that the second opening includes a second ramp portion deflecting outflow from the second opening away from a longitudinal axis of the distal tip in the normal mode (Fig. 23a).

In reference to claim 9, Igarashi discloses that the second opening comprises an expanded section increasing an exit plane cross sectional area of the second orifice (Fig. 23a).

In reference to claim 10, Igarashi discloses that the first and second lumens have substantially D shaped cross sections (Fig. 23b).

In reference to claim 11, Igarashi discloses a contoured bolus including a first ramp substantially aligned with the first opening, a second ramp aligned with the second opening and an atraumatic tip (Fig. 23a).

In reference to claim 12, Igarashi discloses that a maximum radial dimension of the contoured bolus is less than a radius of a catheter to which the distal tip is to be coupled (Fig. 23a).

Claims 16-21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Igarashi et al. (US Patent No. 7,282,041). Igarashi discloses a flow control tip for a multi-lumen catheter comprising: an attachment portion adapted to fluid connect to a distal portion of a catheter (Fig. 23, 100 the attachment portion connects to portion 50 the distal end of a catheter); and a contoured bolus (the examiner is interpreting 12 when inflated as the bolus) defining at least a portion of an inlet and an outlet of the distal tip (Fig. 23 discloses that when 12 is inflated it helps to form the inlet and outlet), so that when coupled to the catheter, the inlet (71) is coupled to a first one of the catheter's lumens (13) and the outlet (81) is coupled to a second one of the catheter's lumens (14), and a flow deflector (54) directing fluids exiting the inlet in a first mode away from the outlet and side walls (Fig. 23a discloses that 54 is angled such that if flow were to exit 71, it would hit 54 and be angled away from the catheter and away from the outlet 81. Fig. 23b also discloses that there are side walls on either side of inlet 71 and outlet 81) extending away from the partition (Fig. 23b discloses that the partition is the horizontal portion of the catheter between lumens 13 and 14 as seen in cross section) on the same side as the inlet (Fig. 23b discloses that there are walls on the same side as the inlet 71) to create a channel between the inlet and the bolus (Fig. 23a discloses that the walls extending upwards from the partition on the sides of the inlet create a channel between the inlet (71) and the bolus (12)), wherein the contoured bolus defines a specified stagger distance between the inlet and the outlet (the distance would be the length of 12).

In reference to claim 17, Igarashi discloses that the contoured bolus further comprises a second flow deflector (the second flow deflector is being interpreted as the top lobe portion of 12, the portion to the right of outlet 81) directing fluid exiting the outlet in a second mode away from the inlet (Fig. 23a discloses that any fluid that exits 81 and happens to come in contact with the second flow deflector, would direct the fluid away from the inlet 71).

In reference to claim 18, Igarashi discloses that the inlet (71) and the outlet (81) are formed on opposite surfaces of the contoured bolus (Fig. 23).

In reference to claim 19, Igarashi discloses that the flow deflector comprises a ramp disposed adjacent an inlet opening (54 is angled and therefore has a ramp portion).

In reference to claim 20, Igarashi discloses that the contoured bolus defines an expanded section oat the outlet increasing an exit plane cross-sectional area of the outlet (Fig. 23a).

In reference to claim 21, Igarashi discloses that a size of the expanded section is selected to reduce an exit pressure of teh fluid to a predetermined level (Fig. 23a).

In reference to claim 23, Igarashi discloses that the attachment portion is adapted for attachment to the catheter by a mechanical/friction fitting (Fig. 23a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Igarashi et al. (US Patent No. 7,282,041) in view of Dasse et al. (US Patent No. 5,171,216). Igarashi discloses the device substantially as claimed, however, Igarashi does not disclose expressly that the stagger distance between the openings is between 1 and 1.5 cm. Dasse, however, discloses a distal tip of a catheter with a stagger distance between the openings.(Fig. 3, 14 and 16) that can be anywhere in the range of 1-4 cm (see col. 5, lines 7-13). Therefore it would have been obvious to one of Ordinary skill in the art at the time of the invention to have modified Igarashi with the stagger distance as specified by Dasse in order to provide an optimal distance between the openings such that mixing of the blood does not occur, yet also to ensure that the distal tip of the catheter can still be maneuverable within a vascular system.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-13, 16-21, 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767